Message

From: Bohnenblust, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0331C49AEB404367AD226F6BD10D795D-BOHNENBLUST]

Sent: 4/23/2020 12:34:39 PM

To: Striegel, Wiebke [Striegel.Wiebke@epa.gov]; Wozniak, Chris [wozniak.chris@epa.gov]

Subject: RE: Oxitec manufacturing establishments

I'm expecting to have this information by noon today. So we need to finish it up and have things in the RA probably by tomorrow at noon at the latest.

Does that seem like a plan. Hopefully this is the only outstanding issue for the RA?

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Striegel, Wiebke <Striegel.Wiebke@epa.gov>

Sent: Thursday, April 23, 2020 8:29 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>

Subject: RE: Oxitec manufacturing establishments

Eric,

I don't know if you have any more insight at this point, but I am wondering how this will fit into the current schedule. I am assuming Chris would need to write up something and I may want to cite his review in the RA.

Wiebke

From: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>

Sent: Thursday, April 23, 2020 8:14 AM
To: Wozniak, Chris < wozniak.chris@epa.gov >
Cc: Striegel, Wiebke < Striegel.Wiebke@epa.gov >
Subject: RE: Oxitec manufacturing establishments

Thanks.

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Wozniak, Chris < wozniak.chris@epa.gov>

Sent: Thursday, April 23, 2020 8:02 AM

To: Bohnenblust, Eric < Bohnenblust. Eric @epa.gov > Cc: Striegel, Wiebke < Striegel. Wiebke@epa.gov > Subject: RE: Oxitec manufacturing establishments

Thanks Eric. It sounds to me like this will work for our review purposes. Chris

Chris A Wozniak, Ph.D.
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From: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>

Sent: Thursday, April 23, 2020 7:53 AM

To: Wozniak, Chris < wozniak.chris@epa.gov>
Cc: Striegel, Wiebke < Striegel.Wiebke@epa.gov>
Subject: FW: Oxitec manufacturing establishments

FYI below is a description of the manufacturing establishments and some background info. If you want any additional description let me know asap so I can communicate back. They plan to submit this as a supplemental MRID but this is a heads up.

Thanks.

Eric Bohnenblust, Ph.D Senior Biologist Emerging Technologies Branch (ETB) Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Nathan Rose < nathan.rose@oxitec.com >

Sent: Thursday, April 23, 2020 7:21 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Cc: kmatthews@wiley.law

Subject: Oxitec manufacturing establishments

Hi Eric and Mike

Here is confirmation by email, as requested, regarding OX5034 manufacturing establishments. The same information will be provided later today in a supplemental volume, as requested.

UK Production facilities are located at:

71 and 37C Innovation Drive, Milton Park, Abingdon, Oxfordshire, United Kingdom, OX14 4RQ. Oxitec's UK facilities are a registered Pesticide Producing Establishment (Establishment No. 93167-GBR-1).

All production of OX5034 eggs will take place in the UK. These processes have been described fully in the relevant volumes and involve rearing female OX5034 to produce eggs, which includes the use of blood feeding to enable females to lay eggs, and tetracycline-class antibiotic usage (specifically, doxycycline) in larval rearing to enable female OX5034 survival to adulthood. Eggs will be shipped to facilities in the USA for adult rearing and field deployment of eggs, as described in the Field Trial Protocol (Section G) of this EUP application.

As described in the Field Trial Protocol (Section G of this EUP application), OX5034 will be deployed in Monroe County, FL and Harris County, TX.

Production facilities in Monroe County, FL will be used for adult rearing of OX5034 male mosquitoes for release. Additionally, components of the Mosquito Rearing Box (e.g. larval diet, etc.) may be formulated from raw materials in this facility, and Mosquito Rearing Boxes assembled for deployment. No egg production (involving blood feeding or tetracycline usage) will take place in this facility, and all OX5034 eggs used will be shipped from Oxitec's UK facilities.

Production facilities will be located at:

Florida Keys Mosquito Control District, 503 107th Street Gulf, Marathon, FL, 33050.

Production facilities in Harris County, TX will be used for adult rearing of OX5034 male mosquitoes for release. Additionally, components of the Mosquito Rearing Box (e.g. larval diet, etc.) may be formulated from raw materials in this facility, and Mosquito Rearing Boxes assembled for deployment. No egg production (involving blood feeding or tetracycline usage) will take place in this facility, and all OX5034 eggs used will be shipped from Oxitec's UK facilities.

Production facilities will be located at:

Mosquito and Vector Control Division, 3330 Old Spanish Trail Bldg. D, Houston, TX, 77021.

Please don't hesitate to ask if you need further information. Kind regards Nathan

Nathan Rose, DPhil Head of Regulatory Affairs Oxitec Ltd 71 Innovation Drive, Milton Park OX14 4RQ, UK +44 (0) 1865 959 883

